EXHIBIT 6

man Pete Stark tatives

Extension of Remarks of Congressman Pete Stark In the House of Representatives October 31, 2000

ABBOTT LABORATORIES OVERCHARGES TAXPAYERS AND JEOPARDIZES PUBLIC HEALTH

Mr. Speaker:

I am today submitting for the Record a letter I sent to Mr. Miles White, Chief Executive Officer of Abbott Laboratories. Recent congressional investigations have collected evidence that Abbott has reported inflated prices and has engaged in other improper business practices in order to create windfall profits for providers submitting Medicare and Medicaid claims for certain Abbott drugs.

Such drug company behavior overcharges taxpayers and jeopardizes the public health system. The letter follows:

FORTNEY PETE STARK

WAYS AND MEANS JOINT ECONOMIC

CONGRESS OF THE UNITED STATES HOUSE OF REPRESENTATIVES WASHINGTON, D.C. 20515

October 31, 2000

Mr. Miles White Chief Executive Officer Abbott Laboratories Dept. 392 APGD 200 Abbott Park Rd. Abbott Park, IL 60064

Dear Mr. White:

You should by now be aware of Congressional investigations revealing that Abbott has for many years reported and published inflated and misleading price data and has engaged in other deceptive business practices. This letter is a call for your company to immediately cease overcharging taxpayers and jeopardizing the public health.

The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price ("AWP") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to in your industry as "the spread." The evidence amassed by Congress clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims.

Contrary to Abbott's recent assertions in the national media, the price manipulation conduct was in no way required by or consistent with existing reimbursement laws or policies. Indeed, Abbott did not falsify published prices in connection with other drugs, where sales and market penetration strategies did not include arranging financial "kickbacks" to health care providers.

In the case of the drugs for which Abbott sought to arrange a financial kickback at the expense of government programs, the manipulated discrepancies between your company's reported AWPs and DPs versus their true costs are staggering. For example, in the 2000 edition of the *Red Book*, Abbott reported an AWP of \$2,094.75 and a DP of \$1,764.00 for a package of Acyclovir Sodium 1 gm. 10's

(package of 10) [NDC # 00074-4452-01], while Abbott was in reality selling the exact same drug to Innovatix members (a large national group purchasing organization) for only \$105.40. This represents a difference between the AWP and cost of \$1,989.35 or a mark up 1987%. (Composite Exhibit "1")¹. I have been informed that Abbott then aggressively marketed its Acyclovir Sodium to health care providers by touting the financial inducements created by the false price representations and other types of monetary payments.

Acyclovir Sodium is an important drug in the treatment of AIDS related illnesses and it is essential that government health programs be able to accurately estimate its acquisition cost in setting reimbursements. Even more devastating, Abbott has intentionally caused the government to pay inflated amounts for this important drug at a time when AIDS health benefits were being limited due to budgetary constraints.

Another example of Abbott's drug price manipulation concerns the IV antibiotic Vancomycin, the drug of last resort in combating many life threatening infections. The public health crisis associated with the overutilization of Vancomycin is now of immediate concern. Exhibit #2, article from Hospital Pharmacist Report entitled UNDER ATTACK VANCOMYCIN-RESISTANT S. AUREUS HITS U.S. SHORES, states:

"The widespread, and often unwarranted, use of antimicrobial agents, particularly vancomycin is a major contributing factor in the emergence of S. aureus with diminished susceptibility to vancomycin.... Published in the MMWR, detailed recommendations for the preventing and controlling S. aureus with diminished susceptibility to vancomycin emphasize strict adherence to contact isolation precautions and the recommended infection control practices, judicious use of vancomycin...and active surveillance for S. aureus with diminished susceptibility to vancomycin" (emphasis added).

Indeed, as stated in the article, the problem has reached the level where the CDC has called for strict limits on the use of this vital drug.

In recent press reports, Abbott attempts to avoid responsibility for financially inducing health care providers to administer Vancomycin. Abbott has suggested that the drug's usage in the outpatient setting is minimal. The evidence developed by the Congressional investigators, however, reveals that outpatient utilization of Abbott Vancomycin has grown substantially in recent years as Abbott inflated its price reports to drug price publishers, while the true price to health care providers fell. Enclosed as Composite Exhibit #3 are excerpts from the Red Book showing Abbott's false price reports for Vancomycin in 1995, 1996 and 1999, together with advertisements available to industry insiders reflecting the lower actual prices. The following chart summarizes this information:

¹ The Exhibits and statistical data cited in this letter were obtained from an industry insider pursuant to a Congressional subpoena.

ABBOTT'S VANCOMYCIN 1 gm. 10s [NDC# 00074-6533-01]

YEAR	RED BOOK AWP	RED BOOK DP	FLORIDA INFUSION TRUE WHOLESALE PRICE	DIFFERENCE BETWEEN AWP & TRUE PRICE "THE SPREAD"
1995	604,44 (60.44 ea.)	•	\$8.40 (ea.)	\$52.04
1996	628.66 (62.86 ea.)		\$7.95 (ea.)	\$54.91
1999	727.82 (72.78 ea.)	612.90	74.00 (\$7.40 ea.)	\$65.38

The evidence uncovered shows that providers will purchase and utilize pharmaceutical manufacturers' products that have the widest spread between the providers' true costs and the reimbursement paid by third parties — including State Medicaid Programs and Medicare. In 1996, Abbott, Fujisawa, Lederle, Lilly and Schein all made representations of Wholesaler Acquisition Cost ("WAC") to the State of Florida, as summarized in the chart below (Exhibit "4"). The chart sets out the reimbursement amount paid by Florida Medicaid, the industry insider's true cost and "the spread" between Medicaid reimbursement and true cost. A review of the chart below clearly demonstrates that the vast majority of providers utilize Abbott's Vancomycin, the drug with the greatest spread between the true wholesaler acquisition cost and the inflated false WAC reported by Abbott.

1996 FLORIDA MEDICAID UTILIZATION FOR VANCOMYCIN HCL 1 GRAM

Company/NDC	True Cost \$	Florida Medicaid Reimbursement	The Spread	Reimbursement Paid by Florida Medicaid	% of Market Share
Abbott 00074-6533-01	\$ 7.95	\$ 58.75	\$50.80	\$ 381,480.78	83.37
Fujisawa 00469-2840-40	\$ 6.42	\$ 13.91	\$ 7.49	\$ 19,023.54	4.16
Lederle 00205-3154-15	\$ 3.98	\$ 9.36	\$ 5.38	\$ 21,297.64	4.65
Lilly 00002-7321-10	\$14.30	\$ 13.35	\$ (0.95)	\$ 19,096.96	4.17
Schein 00364-2473-91	\$ 6.05	> \$ 12.52 /	\$ 6.47	\$ 16,672.18	3.64

Exhibit "5", prepared by the National Association of Medicaid Fraud Controls Units in conjunction with their ongoing investigation, further demonstrates that Abbott maximized sales volume and captured market share by causing 33 State Medicaid Programs to pay substantially inflated reimbursements for Abbott's Vancomycin.

The following document (Exhibit "6") reflects misleading price representations that Abbott sent to Medi Span (now acquired by First Data Bank) concerning two package sizes of Vancomycin. Medi Span's data acquisition specialist attempted to clarify with "Jerrie," from Abbott, the pricing discrepancies and confusion over the prices of the two packages:

"Hi Jerrie!

It's our old buddy Vancomycin again! I am attaching the customer support request that prompted this question because I find it confusing. I know I verified the pricing with you last year, but this customer is convinced our data is incorrect. Here goes...

00074-6533-01 Vancomycin 1gm <u>flip top vial</u>, 10's DP = 529.40 WAC = 380.00 AWP = 635.28

00074-6535-01 Vancomycin 1 gm AddVantage, 10's DP = 190.50 WAC = 169.40 AWP = 228.80

It appears that the only difference between these two products is the vial it comes in. Is this correct? If it is, please let us know why the \$400 plus difference in AWPs? Is one listed wrong? The price does represent 10 vials for both products, doesn't it?

The other thing is that this customer claims he can get Vancomycin for \$6 or \$7 per vial DP as opposed to the \$52.94 and \$19.50 the Abbott Vancomycins cost. <u>Please help me out....(emphasis added).</u>

Regards,

Michelle Christopher
Data Acquisition Specialist"

Abbott's apparent price manipulation created a financial incentive for doctors to increase their usage of Vancomycin, at the very time that overutilization of the drug created a health crisis. This is an especially reprehensible misuse of Abbott's position as a drug manufacturer.

Additionally, as indicated by the evidence below, Abbott has provided or arranged for a number of other financial inducements to stimulate sales of its drugs at the expense of the Medicaid and Medicare Programs. Such inducements include volume discounts, rebates, off invoice pricing, and free goods, and are designed to result in a lower net cost to the purchaser, while concealing the actual cost. For example, a product invoiced at \$100 for ten units of a drug item would in reality only cost the purchaser half that amount if a subsequent shipment of an additional ten units is provided at no charge. The same net result can be achieved through a "grant," "rebate," or "credit memo" in the amount of \$50. The following excerpts from Abbott's internal documents (Composite Exhibit "7") are examples of Abbott's creation of off invoice price reductions that conceal the true

price of drugs and impede the Medicare and Medicaid Programs from accurately estimating the acquisition cost of drugs:

- "1) Purchase 500 cases of standard sets (mix or match) on a single purchase order, receive an additional 50 cases free; purchase 1000 cases, receive additional 150 cases free. Standard set list numbers are 1857-48, 1881-48, and 1859-48.
- 2) Purchase 500 cases of plastic partial fill diluents (mix or match) on a single purchase order, receive an additional 50 cases free; purchase 1000 cases, receive additional 150 cases free. Partial fill list numbers are 7923-36, 7923-37, 7984-36, and 7984-37.
- 3) Purchase 500 cases of butterflies (mix or match from all butterfly list numbers) on a single purchase order and receive an additional 50 cases free; purchase 1000 cases, receive additional 200 cases free.
- 4) Purchase a minimum of \$250K of vancomycin product and receive an additional case free for every 10 purchased. Eligible list numbers are 4332-01 (500mg vial), 6533-01 (1g vial) and 6509-01 (5g vial)."
- " Promotional price is not on invoice but is obtained through the shipment of free goods."

As I am sure you are aware, the inflation index for prescription drugs continues to rise at a rate of more than twice that of the consumer price index. The American taxpayers, Congress and the press are being told that these increases are justified by the cost of developing new pharmaceutical products. Abbott and certain other manufacturers are clearly exploiting the upward spiral in drug prices by falsely reporting that prices for some drugs are rising when they are in fact falling. For example, the actual price being paid by industry insiders for Abbott's drug, Sodium Chloride 0.9%, was in many years less than half of what Abbott represented. Abbott falsely reported that the average wholesale price to health care providers for Sodium Chloride 0.9%, 500 ml 24s, [NDC # 00074-7983-03], rose from \$206.06 to \$229.43 during the years 1993 through 1996. The Congressional investigations have revealed that, in fact, the true price to industry insiders from Florida Infusion was only \$43.20 in 1993 and the price actually fell to \$36.00 by 1996. (Composite exhibit 8).

Abbott's knowledge that true wholesale prices were falling for many of its drugs at the very time that it falsely reported that its prices were rising is evidenced by an internal Abbott document (Exhibit "9") dated March 10, 1994 to a wholesaler, Florida Infusion, which states the following:

"The first three pages, identified as Florida Infusion Price Changes indicate the products in which prices were changed and their new contract price. Favorable factory cost in 1994 have lead the way for these price reductions! (emphasis added).

Shortly after informing Florida Infusion that its prices were being reduced, Abbott falsely informed *Red Book* that its prices were being increased, as evidenced by the internal memo dated May 26, 1994 (Exhibit "10"):

"As you are aware, on at [sic] the beginning of April, Abbott took a list price increase. This also has an effect on our AWP (Average Wholesale Price) which Red Book quotes for reimbursement purposes."

Abbott created and marketed these financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers. Abbott's strategy of using taxpayer funds to increase company drug sales and enriching doctors and others who administer the drugs is reprehensible and a blatant abuse of the privileges that Abbott enjoys as a major pharmaceutical manufacturer in the United States.

Doctors should be free to choose drugs based on what is medically best for their patient. Inflated price reports should not be used to financially induce doctors to administer Abbott's drugs. Abbott's conduct, in conjunction with other drug companies, has cost the taxpayers billions of dollars and serves as a corrupting influence on the exercise of independent medical judgement both in the treatment of severely ill patients and in the medical evaluation of new drugs.

Accordingly, I have requested that the Commissioner of the United States Food and Drug Administration, Dr. Jane Henney, conduct a full investigation into the business practices of certain drug companies, including Abbott. My reading of the Federal Food, Drug, and Cosmetic Act and the corresponding regulations suggests that the FDA should pay particular attention to Abbott's misleading price reports and take affirmative action to ensure that its representations about its drugs are accurate and not misleading.

Abbott is clearly capable of representing prices that do not include a kickback for many of its drugs. The following chart ("Exhibit "11") specifies drugs for which Abbott reported accurate prices:

ABBOTT 1999 REPRESENTATIONS OF PRICES AND COST AND STATES' MEDICALD REIMBURSEMENTS

DRUG STRENGTH & SIZE, NDC# 00074-	RED BOOK AWP	BERGEN BRUNSWIG COST (WAC)	PROVIDER COST with 7% up-charge	FLORIDA MEDICAID WAC + 7%,	NEW YORK MEDICAID AWP-10%,
Biaxin 500mg, 60s NDC2586-60	\$195.59	\$164.13	\$175.62	\$175.62 Spread \$0.00	\$176.04 Spread \$0.42 (0.2%)
Cartrol 5mg, 100s NDC,1665-13	\$106.18	\$88.76	\$94.97	\$94.97 Spread \$0.00	\$95.57 Spread \$0.60 (0.6%)
Cylert Tablets 37.5mg,100s NDC6057-13	\$144.84	\$121.67	\$130.18	\$130.18 Spread \$0.00	\$130.36 Spread \$0.18 (0.1%)
Depakote 250mg, 100s NDC6214-11	\$82.66	\$69.30	\$74.15	\$74.15 Spread \$0.00	\$74.40 Spread \$0.25 (0.3%)

As illustrated by the preceding information, Abbott clearly has the ability to accurately and competently report its prices and consistently did so when it was in its own economic interest.

I urge Abbott to immediately cease reporting inflated and misleading price data. Such action places the nation's health care at great risk and overcharges taxpayers.

Based on the evidence collected, Abbott should make arrangements to compensate taxpayers for the financial injury caused to federally funded programs. Any refusal to accept responsibility will most certainly be indicative of the need for Congress to control drug prices. If we cannot rely upon drug companies to make honest and truthful representations about their prices, then Congress will be left with no alternative but to take decisive action to protect the public.

I would appreciate your sharing this letter with your Board of Directors and in particular with the Board's Corporate Integrity Committee.

Pete Stark

Member of Congress

Enclosures